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INTRODUCTION

The United States brings this enforcement action to prevent Fresenius, a sophisticated corporation well-versed in privilege log discovery disputes, from evading its responsibility to fully comply with legitimate administrative subpoenas by hiding behind massive privilege logs that shirk basic requirements. By repeatedly failing to provide an adequate privilege log, Fresenius Medical Care Holdings, Inc., Fresenius Medical Care Pharmacy Services, Inc., and Fresenius Medical Care Rx, LLC (collectively, “Fresenius”) have delayed by approximately fifteen months a health care fraud investigation by the Department of Health and Human Service Office of Inspector General (“HHS-OIG” or “the United States”)¹ of Fresenius.

HHS-OIG issued subpoenas 17498, 17499, and 17500 (the “Subpoenas”)² to Fresenius in good faith under the Inspector General Act as part of an investigation undertaken by HHS-OIG to fulfill its duty to investigate fraud and abuse on federal healthcare programs. Specifically, the Subpoenas seek information and documents relevant to Fresenius’ practices concerning patient co-payment waivers, returned medications, and auto refills. The United States worked with Fresenius to negotiate the scope of Fresenius’ subpoena responses, including matters related to e-discovery. As part of these discussions, the United States agreed to exclude data HHS-OIG had received from Fresenius in response to a subpoena in a different matter. During the subsequent e-discovery negotiations, Fresenius abruptly agreed to individual custodians and search terms but proposed a review methodology under which it would forego a responsiveness review of all emails that were not potentially privileged, and thus, shift this burden to the United States. It was, of course, still necessary for Fresenius to identify and review potentially privileged documents, and it designed

¹ The United States Department of Justice represents HHS-OIG in this investigation of Fresenius.

² Subpoenas 17498, 17499, and 17500 were issued respectively to Fresenius Medical Care Holdings, Inc., Fresenius Medical Care Pharmacy Services, Inc., and Fresenius Medical Care Rx, LLC

a process for doing so. During these negotiations and subsequent document productions, Fresenius never objected to the Subpoenas' relevance, reasonableness, or burden. And only after the United States questioned the glaring deficiencies in Fresenius' first privilege log did Fresenius start complaining about the burdens of preparing a log.

After the United States insisted that glaring deficiencies in Fresenius' first, and then its second, privilege logs be fixed, Fresenius is now on its third privilege log. So Fresenius has already had two chances to revise its inadequate logs, but the third privilege log has the same egregious deficiencies. Fresenius refuses to provide basic, mandatory information that the United States needs to assess Fresenius' privilege assertions. It refuses to identify third-parties and non-legal personnel by providing any information on their roles or capacities. Fresenius does not identify any potential litigation at issue in every communication it maintains is protected by the attorney work product doctrine. Similarly, for thousands of communications over which it asserts attorney-client privilege, Fresenius fails to specify the nature of the legal issue addressed. Fresenius also continues to assert attorney-client privilege over hundreds of communications that were not sent to or from an attorney, or included an attorney in copy only, without explaining how these documents were communications with legal advisors for the purpose of obtaining legal advice. Without this basic information, the United States cannot assess the validity of Fresenius' privilege claims.

Fresenius' blatant disregard for basic privilege log requirements is a tactic it has previously used to dodge its discovery obligations. Just eighteen days before Fresenius produced its first grossly deficient privilege log to the United States, the Supreme Court of Mississippi upheld a sanction against Fresenius that waived all asserted privileges based on the same types of persistent

deficiencies that have left the United States with no option other than to initiate this enforcement action. *See generally Fresenius Medical Care Holdings, Inc. v. Hood*, 269 So. 3d 36 (Miss. 2018).

Summary enforcement of the Subpoenas here is necessary, because Fresenius has significantly, unjustifiably, and prejudicially delayed HHS-OIG's investigation by blatantly disregarding basic privilege log requirements. Fresenius' repeated refusal to produce an adequate privilege log reflects bad faith given that it just recently spent years litigating – and ultimately losing – disputes over the same types of deficiencies that remain in its third privilege log. Even though Fresenius had three chances to provide an adequate privilege log, its third bite at the apple remains inadequate. The egregious and continuing deficiencies remaining in Fresenius' third privilege log warrant a finding that Fresenius has waived the privileges asserted there.

STATEMENT OF FACTS

HHS-OIG is investigating whether Fresenius committed fraud or abuse on federal healthcare programs by giving kickbacks to patients in the form of improper co-payment waivers, improperly automatically refilling certain prescriptions, and billing for prescriptions that were not authorized or accepted by federal healthcare program beneficiaries. Decl. of Special Agent Richard Haines ("Haines Decl."), ¶ 5. On May 2, 2017, HHS-OIG issued subpoenas *duces tecum* 17498, 17499, and 17500, respectively, to Fresenius Medical Care RX, LLC, Fresenius Medical Care Pharmacy Services, Inc., and Fresenius Medical Care Holdings, Inc. *Id.*, ¶ 3, Ex. 1-3. On May 8, 2017, a Fresenius attorney accepted service of the Subpoenas. *Id.*, ¶ 11, Ex. 4.

The Subpoenas provided clear instructions for withholding documents based on privilege. They explained that any documents withheld based on privilege should be identified on a privilege log that included information such as the name and title of the author and any recipients of the document, the document date, a brief description of the subject matter, a statement explaining the basis for the privilege claims, and the document request to which the document was responsive.

See, e.g., id., ¶ 7, Ex. 1-3 at pt. II(4). While negotiating the scope of its responses, including e-discovery searches and review methodology, Fresenius never sought to modify the Subpoenas' requirements for privilege logs. Decl. of Ellen Bowden McIntyre ("McIntyre Decl."), ¶ 6.

Fresenius and the United States began negotiating the scope of e-discovery in June 2017. *Id.*, ¶¶ 7-8, Ex. 1. Over several months, Fresenius and the United States negotiated search terms and custodians for Fresenius' e-discovery searches and reviews. *Id.*, ¶¶ 8-11, Ex. 1-4. During these negotiations, the United States agreed to exclude from production certain emails Fresenius had previously produced to the United States in response to requests in another matter in another state. *See id.* ¶ 7, Ex. 5. On August 14, 2017, the United States provided an updated proposal for custodians and search terms and indicated it "look[ed] forward to [Fresenius'] response." *See id.*, ¶ 9, Ex. 2. When the United States had not heard back from Fresenius after several months, it followed up via email. *See id.*, ¶ 10, Ex. 3.

The next day Fresenius suddenly abandoned further negotiations about the scope of search terms and custodians. Fresenius reported that the search terms and custodians at issue resulted in a volume of 71,776 emails and attachments. Fresenius acknowledged, however, that its email collection and volume analysis was incomplete, such that the anticipated volume "will increase." Nevertheless, Fresenius accepted the United States' August 14th proposal for custodians and search terms without further negotiation. *See id.*, ¶ 11, Ex. 4.

Fresenius also indicated – for the first time – that it would produce all documents that hit on search terms for the agreed custodians without a responsiveness review, unless a document contained potentially privileged material. *Id.* Fresenius said that it would identify potentially privileged material by applying search terms designed to identify potentially privileged communications, such as the names of individual lawyers or outside law firms ("Privilege Search

Terms”). *See id.* Documents containing Privilege Search Terms would be segregated for a responsiveness and privilege review. *See id.* Thus, Fresenius sought to reduce the burden associated with a responsiveness review – and shift this burden to the United States. The United States did not object to this methodology. *See id.*, ¶ 12. But Fresenius never indicated it would not comply with the Subpoenas’ instructions for providing privilege logs and did not ask to modify the requirements for privilege logs. *See id.*, ¶ 6.

Fresenius made its first email production on November 21, 2017 and its second email production on February 20, 2018. *See id.* ¶ 13, Ex. 5-6. The cover letters for these two email productions reiterated that Fresenius would provide a supplemental production and privilege log after reviewing documents that were segregated for review because they contained a Privilege Search Term. In neither letter did Fresenius indicate it would compile its privilege log in a manner other than as specified in the Subpoenas. *Id.*

Seven months later, on October 22, 2018, Fresenius provided its first meager effort at a privilege log (the “First Privilege Log”).³ *Id.*, ¶ 16, Ex. 7. The massive First Privilege Log contained *526 pages with 6,023 line entries*. After devoting substantial time and resources attempting to decipher Fresenius’ First Privilege Log, the United States notified Fresenius that the First Privilege Log did not comply with the Federal Rules of Civil Procedure, the instructions provided in the Subpoenas, or relevant case law. *See id.*, ¶ 18, Ex. 8 at 1. On February 13, 2019,

³ In the October 22, 2018 cover letter, Fresenius notified the United States – for the first time – that it continued to withhold certain documents for further evaluation of potential issues raised by the European Union’s General Data Protection Regulation (“GDPR Documents”). Fresenius claimed that this was the only “small subset of documents” it was continuing to review in response to the May 2017 Subpoenas. *Id.* ¶ 16, Ex. 7 (10/22/18 ltr.). Despite assurances that the GDRP issues affected only a “small” amount of documents, Fresenius later informed the United States that there were in fact 2,100 documents at issue. *Id.* ¶ 24, Ex. 12 (8/1/19 ltr.). Fresenius has since determined that it will not produce these materials to the United States. It has not, however, provided any privilege log whatsoever with respect to the GDPR Documents. *See id.*

the United States sent Fresenius a letter outlining the First Privilege Log's numerous deficiencies preventing analysis of Fresenius' privilege assertions, including Fresenius':

- failure to provide any information whatsoever on the roles or capacities of the authors or recipients included on the privilege log, *Id.* at 3;
- failure to include separate entries for emails and their attachments, *Id.* at 3-4;
- failure to differentiate individual emails within email chains, *Id.* at 5; and
- vague document descriptions supporting attorney-client privilege claims and failure to establish whether the communications were made for the purpose of obtaining legal advice rather than ordinary business advice, *see, e.g., id.* at 3-4.

Additionally, the United States noted deficiencies with privilege claims over redacted material and requested a separate redaction log. *Id.* at 6-8. The United States asked Fresenius to respond to these concerns and offered Fresenius an opportunity to revise its initial log. *Id.* at 8.

On February 27, 2019, Fresenius responded suggesting that the shortcomings of its privilege log were appropriate "given the total production volume and total review population." *Id.*, ¶ 20, Ex. 9 at 1. In this letter, Fresenius provided – for the first time – an updated volume analysis generated from the e-discovery search terms and custodians, which Fresenius itself had agreed to before completing its collection and volume analysis. Specifically, Fresenius informed the United States that its total volume of documents returned from the search terms had ballooned beyond the 71,776 documents (including emails and families) that it reported on November 7, 2017. *Compare id.*, ¶ 11, Ex 4. *with id.* ¶ 20, Ex. 9 at 1-2. Fresenius explained it had already produced more than 162,000 email families that hit on a search term. Also, Fresenius reported – for the first time – that 155,000 documents included a Privilege Search Term, and thus, had been reviewed for responsiveness and privilege under the search and review methodology it had proposed. *Id.*, Ex. 9 at 1-2. Notably, Fresenius only provided these statistics after it had

purportedly finished the vast majority of its email production on October 22, 2018.⁴ Fresenius had never before informed the United States of – much less complained about – the volume of email generated from the search terms and custodians it had agreed to, nor the email volume under Fresenius’ own methodology. Thus, Fresenius’ complaints about these matters began only after the United States identified deficiencies with the privilege log.

Following the United States’ complaints about the First Privilege Log, Fresenius agreed to revise it to address *some* of the United States’ concerns. Fresenius agreed to provide an index of in-house and outside legal personnel, log emails and attachments separately, and provide a redaction log. *Id.*, ¶¶ 20-21, Ex. 9. But Fresenius did not agree to identify any other individuals listed in the log. Fresenius also failed to address the United States’ concerns about its failure to provide document description details sufficient to show that the documents were communications made to obtain legal advice, rather than ordinary business communications. *See id.*

Thus, unsurprisingly, when Fresenius provided a revised, second privilege log on May 10, 2019 (the “Second Privilege Log”), more than three months after the United States notified it of the original deficiencies, the new log suffered from many of the same defects. *See id.*, ¶ 22, Ex. 10. The Second Privilege Log had 12,542 line entries,⁵ and provided an index of in-house and outside legal personnel. *Id.*, ¶ 23. At the same time, Fresenius produced an additional 910 documents over which it had initially asserted privilege, which represents approximately fifteen percent of the 6,023 documents included on the First Privilege Log. *Id.*, ¶ 23. Despite the three-month delay, Fresenius still failed to address many deficiencies.

⁴ As noted previously, in its October 22, 2018 letter, Fresenius noted it was continuing to withhold the GDPR documents. *Id.*, ¶ 16, Ex. 7.

⁵ The number of entries increased substantially between the First and Second Privilege Logs because Fresenius agreed to log emails and their attachments separately, as it should have done initially.

After again undertaking an extensive review of the Second Privilege Log, on July 30, 2019, the United States informed Fresenius that there remained insufficient information to assess Fresenius' privilege claims. *See id.* ¶ 24, Ex. 11 at 3. The United States noted that most of the thousands of entries were missing required elements, such as the document's author, recipient, or title. The United States also explained that the log did not clarify which documents were emails versus attachments to emails. The United States further identified an issue in which a large number of apparent attachments (which appear in the log in the row after the preceding document, but are were confusingly not labeled as attachments) were dated *after* the apparent parent email – a chronological impossibility. Finally, the United States warned Fresenius that it was considering asking for court review of the privilege log. *Id.*

On August 14, 2019, Fresenius informed the United States that it was working on a response to the privilege issues identified by the United States. *See id.* ¶ 27, Ex. 13. On August 23, 2019, Fresenius emailed Assistant U.S. Attorney (AUSA) Ellen Bowden McIntyre, stating that it would soon respond as to the privilege and redaction logs. *Id.*, ¶ 28, Ex. 14. When Fresenius did not respond further, on September 12, 2019, the United States requested a call the next day. *See id.*, ¶ 29, Ex. 15. The United States informed Fresenius that if it did not have a written response on the privilege log issues by September 23, 2019, it would file an action to enforce the Subpoenas. *Id.* Counsel for Fresenius then agreed to hold a call on September 13, 2019. *Id.*, ¶ 30.

Fifteen minutes before the scheduled September 13, 2019 call, Fresenius' counsel sent a long letter responding to the issues the United States had raised on July 30, 2019. *Id.* ¶ 31, Ex. 16-17. Fresenius explained that it had previously relied on metadata to populate many of the privilege log fields, and it was now conducting a “manual review” to provide information that had not been included in prior versions of the log, such as attachment authors or creators, attachment recipients,

and attachment titles. *Id.*, Ex. 17 at 2-3. Fresenius could not explain why certain attachments postdated the parent emails. *Id.* at 3. While Fresenius acknowledged that it had not yet undertaken a human review to provide this required information, it nevertheless complained about the burden of creating and amending the log. *Id.* at 1-2. Fresenius' counsel stated that the "manual review" was approximately halfway complete and that they expected to provide updated privilege logs by September 30, 2019. *Id.*, Ex. 17.⁶

Fresenius completed its production of a second revised privilege log on September 30, 2019 (the "Third Privilege Log"). After another comprehensive review, the United States has identified the following persistent deficiencies with the Third Privilege Log:

- Fresenius has still not identified third-parties and non-legal personnel by providing any information on their roles or capacities;
- Fresenius does not specify any potential litigation at issue in every single one of the 161 communications over which it asserts attorney work product;
- Fresenius' descriptions for thousands of communications over which it asserts attorney-client privilege are so vague that they fail to specify the nature of the legal issue addressed; and
- Fresenius continues to assert attorney-client privilege over more than a thousand communications that were not sent to or from an attorney, or merely copied an attorney, without explaining how these documents were communications with legal advisors seeking legal advice.

Id. ¶¶ 35-43 & Ex. 20. Thus, fifteen months after Fresenius ostensibly completed its email production and provided its first log, the United States remains unable to assess the privileges asserted in the 12,506 entries of the Third Privilege Log. *See id.* To illustrate the nature of these deficiencies, the United States has attached two filtered versions of the massive Third Privilege Log to the McIntyre Declaration: Exhibit 22, which is a subset of the log with all entries asserting

⁶ Because the United States did not have time to review the letter in advance of the scheduled call, Fresenius and the United States held only a brief call in which Fresenius reiterated the points in its letter. *Id.* ¶ 32.

work product protection, and Exhibit 23, which is a Sample Log highlighting exemplar entries that are deficient as to their privilege assertions. After exhausting informal attempts to resolve the matter, the United States has filed the instant petition.

ARGUMENT

I. THE UNITED STATES HAS MET THE STANDARD TO SUMMARILY ENFORCE THE SUBPOENAS

The Inspector General Act (the “Act”) provides that when the recipient of an administrative subpoena refuses to comply, the subpoena “shall be enforceable by order of any appropriate United States district court.” 5 U.S.C. app. 3 § 6(a)(4). The Sixth Circuit has “emphasized that a district court’s role in the enforcement of an administrative subpoena is a limited one.” *United States v. Markwood*, 48 F.3d 969, 976 (6th Cir. 1995). A district court must enforce an administrative subpoena so long as: (1) the subpoena satisfies the terms of the authorizing statute; (2) the information or documents requested are reasonably relevant to the agency’s investigation; (3) the information sought is not already in the agency’s possession; and (4) enforcement of the subpoena will not abuse the court’s process. *In re Admin. Subpoena John Doe v. United States*, 253 F.3d 256, 265 (6th Cir. 2001) (citing *Markwood*, 48 F.3d at 976).

Proceedings to enforce an administrative subpoena must be limited in scope to protect “the important governmental interest in the expeditious investigation of possible unlawful activity.” *Markwood*, 48 F.3d at 976. To ensure the summary nature of enforcement proceedings, the United States is authorized to rely on declarations to meet the requirements for enforcing an administrative subpoena. *In re EEOC*, 709 F.2d 392, 400 (5th Cir. 1983). Here, the Declarations of Agent Haines and AUSA McIntyre demonstrate that summary enforcement is proper.

A. The Subpoenas Satisfy the Terms of the Inspector General Act

The Subpoenas satisfy the terms of the authorizing statute, the Inspector General Act. Pursuant to this Act, HHS-OIG has a “duty and responsibility” to conduct audits and investigations to prevent and detect fraud and abuse. 5 U.S.C. app. 3 § 4(a). The Act also authorizes HHS-OIG to issue subpoenas for the production of information and documents needed for HHS-OIG to fulfill its responsibility to prevent and detect fraud and abuse. 5 U.S.C. app. 3 § 6(c)(4).

HHS-OIG is investigating whether Fresenius engaged in fraud or abuse with respect to three distinct billing practices. From 2011 through 2018, federal healthcare programs including Medicare paid Fresenius nearly one billion dollars for prescription drugs. HHS-OIG’s investigation of certain billing practices by Fresenius is undertaken to ensure Fresenius did not obtain any portion of these funds through fraudulent or abusive practices, including conduct that would violate various federal and state healthcare laws. *See* Haines Decl. at 2.

First, HHS-OIG is investigating whether Fresenius provided co-payment waivers for prescription medications to federal healthcare benefit program beneficiaries in violation of the Anti-Kickback Statute (“AKS”) and the False Claims Act (“FCA”). *See* Haines Decl. at 2. The AKS prohibits payment of any remuneration, including any kickback, bribe, or rebate, to any person to induce that person to purchase goods or services that will be paid for under a federal healthcare program. 42 U.S.C. § 1320a-7b(b). And, “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g). Co-payment waivers can violate the AKS and lead to FCA violations when one of their purposes is to induce beneficiaries of government healthcare programs to order goods or services, such as prescription medications. *See* 42 U.S.C. § 1320a-7a(i)(6) (“remuneration” under the AKS includes “the waiver of coinsurance and deductible amounts”);

see also United States ex rel. Strunck v. Mallinckrodt ARD LLC, 2020 WL 362717, at *4 & 7 (E.D. Pa. Jan. 22, 2020) (denying motion to dismiss FCA suit alleging copay waivers and finding such kickbacks *per se* material); *United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 499 n.3 (D.S.C. 2016) (United States sufficiently alleged AKS-predicated FCA violation by alleging the defendant “waived copays ‘with the intent to induce . . . referrals.’”).

HHS-OIG is also investigating two other interrelated practices: (1) whether Fresenius billed federal healthcare programs for prescription medications that were filled through its automatic refill program, but were not authorized or not accepted by the beneficiaries and (2) whether Fresenius auto refilled medications in violation of state Medicaid requirements. *See Haines Decl.* at 2. Inappropriate refill practices, such as push-billing and automatic refills, create a risk for fraud, waste, and abuse. *See Centers for Medicare & Medicaid Services, Pharmacy Self Auditing: Control Practices to Improve Medicaid Program Integrity and Quality Patient Care – Booklet 4: Billing Practices*, at 7 (December 2015), *available at* <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/pharmacy-selfaudit-booklet4-billing-practice.pdf>. Indeed, many Medicaid programs prohibit pharmacies from automatically refilling prescriptions paid by Medicaid. *See, e.g., State of Tennessee Medicaid Pharmacy Claims Submission Manual*, *available at* https://tenncare.magellanhealth.com/static/docs/Program_Information/TN_Medicaid_Pharmacy_Claims_Submission_Manual_Final.pdf. Thus, improper uses of co-payment waivers, automatic refills, and billing for refused medications can result in health care fraud. HHS-OIG undertook its investigation of Fresenius to carry out its duty to prevent fraud and abuse as required by the Act.

Furthermore, the Subpoenas were issued pursuant to HHS-OIG’s authority under the Act to obtain documents necessary for HHS-OIG to fulfill its responsibility to prevent and detect fraud

and abuse. HHS-OIG subpoenas satisfy the terms of the Act when they are issued as part of an HHG-OIG inquiry focused on whether fraud or abuse has occurred. *See* 5 U.S.C. app. 3 § 6(c)(4); *United States v. Lilburn Geriatric Ctr., Inc.*, 2003 WL 27381235 (N.D. Ga. Sept. 23, 2003) (“as long as the OIG-HHS’s inquiry is focused on whether fraud has occurred, subpoenas issued pursuant to that inquiry would appear to be within its authority”). The Subpoenas seek information and documents necessary to its investigation focused on whether fraud or abuse occurred with respect to Fresenius’ use of co-payment waivers, automatic refills, and refused medications. *See* Haines Decl. at 3-4. Therefore, the Subpoenas satisfy the terms of the Act.

B. The Information and Documents Sought by the Subpoenas Are Reasonably Relevant to the HHS-OIG Investigation

The information and documents sought by the Subpoenas are reasonably relevant to HHS-OIG’s investigation. The Sixth Circuit requires that courts construe relevance broadly and “show deference to the statutory authority of administrative agencies to perform investigatory functions.” *Markwood*, 48 F.3d at 977. Consequently, administrative subpoenas must be enforced when “the evidence sought by the subpoena [is] not plainly incompetent or irrelevant to any lawful purpose of the [agency] in [its] duties.” *Id.* (quoting *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943); *see also In re McVane*, 44 F.3d 1127, 1135 (2d Cir. 1995) (courts must “defer to the agency’s appraisal of relevancy” unless it is “obviously wrong”). Courts may “weigh the likely relevance of the requested material to the investigation against the burden . . . of producing the material” in determining the appropriate scope of the request. *In re Admin. Subpoena James Smith v. United States*, 289 F.3d 843 (6th Cir. 2001) (quotations omitted).

The Subpoenas seek documents and information that HHS-OIG needs to determine if Fresenius has engaged in conduct that is fraudulent or abusive on federal healthcare programs, including violations of the AKS or FCA. The Subpoenas seek documents and communications

regarding Fresenius' policies and procedures on co-payment waivers, automatic refills, and refused medications to enable HHS-OIG to determine whether they were compliant with federal and state healthcare laws. *See* Haines Decl., Ex. 1-3 (document requests 4, 5, 6, 7, 8, 10 and 15). In addition, the Subpoenas seek various documents designed to elicit information to help HHS-OIG determine if Fresenius' actual practices or incentives relating to co-payment waivers, automatic refills, and refused medications were consistent with its formal policies and procedures as well as federal and state healthcare laws. *See id.* (document requests 3 and 14 (bonuses), 7 (bad debt), 9 (advertising), 12 and 13 (budget/revenue), 15 and 22 (compliance/training/audits), 16 and 18 (government disclosures, internal complaints), 17 (call logs about returned or refused medications), 19 (write-offs), and 21 (emails)). Other requests in the Subpoenas seek documents or information to enable HHS-OIG to determine whether false claims have been submitted to the United States due to improper co-payment waivers or automatic refills. *See id.* (document requests 20 (patient records) and 23 (claims data)). Finally, the Subpoenas seek corporate documents and communications that would enable HHS-OIG to determine if Fresenius engaged in any such improper conduct with actual knowledge, reckless disregard, or deliberate ignorance. *See id.* (document request 11 (board materials)). Thus, the Subpoenas request information relevant to determining if Fresenius has engaged in any fraudulent or abusive practices or AKS or FCA violations.

The Subpoenas are not unreasonable or burdensome. The heavy burden of showing that an administrative subpoena is unreasonable falls upon the subpoenaed party. *F.T.C. v. Texaco, Inc.*, 555 F.2d 862, 882 (D.C. Cir. 1977). When "the agency inquiry is pursuant to a lawful purpose and the requested documents are relevant to that purpose," the respondent's "burden is not easily met." *Id.* As a condition to finding a subpoena overly broad or burdensome, courts require the

respondent to “attempt to reach a reasonable accommodation with the government.” *Doe*, 253 F.3d at 268-269 (citations omitted).

Here, Fresenius has never asserted that the Subpoenas seek irrelevant information or that they are unreasonable or burdensome. McIntyre Decl. at 2. To the extent that Fresenius has sought to limit its scope of production, the United States negotiated an accommodation to its requests. For example, Fresenius and the United States negotiated and agreed upon search terms and custodians for e-discovery. *Id.* at 2-3. The United States also agreed to obtain access to emails Fresenius produced to the United States in connection with a separate matter, rather than requiring that Fresenius produce these materials to HHS-OIG. *Id.* at 2. Fresenius never subsequently sought any additional accommodations to limit the scope of the Subpoenas. *Id.*

Tellingly, Fresenius only recently complained about the burden of producing a privilege log. Fresenius did not raise these concerns until after it had completed its email production and only after the United States challenged the adequacy of its original privilege log and then its revised privilege log. Fresenius’ complaints came 2.5 years after it received the Subpoenas and nearly two years after Fresenius reached an agreement with the United States regarding e-discovery methodology, which included a process for reviewing potentially privileged documents which Fresenius itself developed and proposed. *Id.* at 2-3. Despite its complaints about the efforts associated with producing a privilege log pursuant to its own proposed methodology, Fresenius has never objected to the relevance, reasonableness, or burden of the Subpoenas themselves. *Id.* at 2. As such, the subpoenaed records are reasonably relevant to HHS-OIG’s investigation.

C. HHS-OIG Has Agreed to Exclude from Production Documents It Already Possessed

When the other elements for enforcement are satisfied, a district court must enforce an administrative subpoena for information that is “not already in the agency’s possession.” *Doe*, 253 F.3d at 265. Shortly after service of the Subpoenas, on June 19, 2017, the United States and

Fresenius held a conference call about e-discovery search terms and custodians. On the call, Fresenius told the United States that it had already produced emails from certain custodians to the United States in connection with a separate, prior matter. The United States agreed to exclude those materials from productions responsive to the instant Subpoenas. *See McIntyre Decl.*, Ex. 5 (Fresenius letter confirming that it “excluded from [its email] production set those documents that were already produced . . . in the separate matter as [the United States] indicated on our conference call on June 19, 2017, that [it] already had access to these documents and did not need them to be re-produced.”). Thus, HHS-OIG agreed to exclude documents the United States already had here.

D. Enforcing the Subpoenas Will Not Constitute an Abuse of the Court’s Process

The Court’s process will not be abused if the Subpoenas are enforced. A court’s process is abused when a subpoena is “‘issued for an improper purpose, such as to harass the [subpoena recipient] or to put pressure on him to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation.’” *Doe*, 253 F.3d at 272 (citing *United States v. LaSalle Nat’l Bank*, 437 U.S. 298, 316 (1978)). A subpoena respondent bears the heavy burden of establishing bad faith. *Id.* Bad faith requires a showing of more than “improper motives of an individual agency employee,” but rather requires a showing that “the agency itself, in an institutional sense, acted in bad faith when it issued the subpoena.” *Id.*

Here, HHS-OIG acted in good faith and with a proper purpose in issuing the Subpoenas. *See Haines Decl.* at 3-4. HHS-OIG issued the Subpoenas under its authority to conduct investigations of fraudulent or abusive practices in federal healthcare programs. *Id.* at 1 & 3. Furthermore, the United States has given Fresenius multiple opportunities to comply with the Subpoenas. *See McIntyre Decl.* at 4-5. Fresenius has never indicated that the Subpoenas were improper or issued in bad faith. *See id.* at 2 & *Haines Decl.* at 4. To the contrary, after each time

the United States has identified deficiencies in Fresenius' responses to the Subpoenas, Fresenius has revised its responses. *See* McIntyre Decl. at 4 & 6. The United States also gave Fresenius notice that it would pursue an enforcement action to address the continued deficiencies with its privilege logs. *See id.* at 5 & 7. So enforcing the Subpoenas will not abuse the Court's process.

The Subpoenas satisfy the terms of the Act because they were issued by HHS-OIG to carry out its responsibility to prevent and detect fraud and abuse. The Subpoenas request documents relevant to HHS-OIG's inquiry, and they are not unreasonable or burdensome. Enforcing them would not abuse the court's process, because they were issued in the good faith pursuit of the investigation. Thus, the Subpoenas should be summarily enforced.

II. THE THIRD PRIVILEGE LOG STILL HAS EGREGIOUS DEFICIENCIES

Fresenius' Third Privilege Log remains inadequate because it does not include sufficient factual information to assess whether the privileges asserted apply to the underlying documents. "The burden to establish the applicability of privilege is upon the [party asserting privilege]." *United States v. Moss*, 9 F.3d 543, 550 (6th Cir. 1993). To justify an assertion of privilege, the party asserting privilege must produce a privilege log with sufficient factual detail to allow opposing counsel to assess and, ultimately, the court to determine whether the elements of the privilege are satisfied. *See Brubaker v. Encompass Prop. & Cas. Co.*, 2008 U.S. Dist. LEXIS 40133, at *2 (E.D. Mich. May 19, 2008) ("There also must be enough detail to allow opposing counsel to intelligently argue that the privilege does not exist."); *Mafcote, Inc. v. Federal Ins. Co.*, 2010 WL 1929900, at *5 (W.D. Ky. May 12, 2010) ("a privilege log must contain sufficient factual content to allow the court to reach the conclusion that each element of that privilege is fulfilled.").

Courts in the Sixth Circuit and elsewhere require that privilege logs identify the following elements: "(a) The author(s) and all recipients (designated so as to be clear who is the sender and

who is the receiver), along with their capacities/roles/positions; (b) The document's date; (c) The purpose and subject matter of the document; and (d) The nature of the privilege asserted, and why the particular document is believed to be privileged.” *Polylok, Inc. v. Bear Onsite, LLC*, 2017 WL 1102698, at *6 (W.D. Ky. Mar. 23, 2017) (collecting cases from courts in the Sixth Circuit).

Although Fresenius has revised its privilege log twice – and only after the United States identified various deficiencies in prior drafts – the Third Privilege Log still lacks sufficient detail to assess if the elements of the asserted privileges apply to the underlying document. First, the Third Privilege Log does not specify the vast majority of the email participants by their capacity, roles, or positions. Second, Fresenius' descriptions of the emails' subject matters are not detailed enough to determine if the asserted privilege applies. Third, Fresenius has not provided sufficient information to determine whether numerous communications over which it has asserted attorney-client privilege were actually communications sent or received by legal advisors for the purpose of obtaining or providing of legal advice. Therefore, the Third Privilege Log remains deficient.

A. The Third Privilege Log Does Not Sufficiently Identify Individuals Who Authored or Received the Allegedly Privileged Documents

The Third Privilege Log remains inadequate because it does not provide information on the capacities, roles, or positions of the vast majority of authors and recipients included on the log. Courts consistently require that privilege logs specify the “capacities/roles/positions” of “[t]he author(s) and *all* recipients” of documents withheld on the basis of privilege. *Id.* at *6 (emphasis added); *In re Veiga*, 746 F. Supp. 2d 27, 40 (D.D.C. 2010) (party ordered to produce documents when its privilege log offered only vague descriptions of individuals or provided no description of an individual at all, which “left [the court] to guess as to the role and relationship of various individuals, including several non-lawyer, third parties”); *United States ex rel. McGee v. IBM Corp.*, 2017 WL 1232616, at *2 (N.D. Ill. Apr. 4, 2017) (ordering party to “produce a privilege

log that identifies the capacities of each author and recipient at the time the document was composed and distributed”); *Firefighters’ Ret. Sys. v. Citco Grp. Ltd.*, 2018 WL 305604, at *7 (M.D. La. Jan. 5, 2008) (party claiming privilege required to provide “the position and/or function of each individual named on the Defendants’ privilege log”); *Clark Const. Group, Inc. v. City of Memphis*, 2005 WL 6187896, at *3 (W.D. Tenn. Feb. 9, 2005) (privilege log insufficient with only “general categories of persons and entities without identifying anyone by name and position”).

Fresenius has resisted, and continues to resist, providing basic information about the roles of the individuals included on its privilege logs. Fresenius’ First Privilege Log failed to provide any information whatsoever regarding the authors and recipients, including no indication regarding which participants were legal personnel. *See McIntyre Decl.*, ¶ 17. Only after the United States requested an index of the capacities, roles, or positions of all individuals on the privilege log, did Fresenius produce a partial index of individuals on the privilege log (the “First Index of Legal Persons”). *Id.*, ¶¶ 17 & 22. The First Index of Legal Persons included a list of 81 legal personnel and their positions, but it did not include any information regarding non-attorneys. *Id.*, ¶ 22. More than six months later, after the United States identified persistent deficiencies in the Second Privilege Log, Fresenius amended its index to add five additional legal personnel (the “Second List of Legal Persons”). *Id.*, ¶ 36 & Ex. 21. The second index, however, remains incomplete because Fresenius continues to refuse to provide information on the capacities, roles, or positions of non-legal personnel who authored or received the documents. *Id.*

Fresenius’ refusal to include the roles of non-legal personnel makes it impossible to assess Fresenius’ privilege assertions. For example, regarding Fresenius’ attorney-client privilege claims, the United States cannot determine if communication were made in confidence or for legal advice. *See Veiga*, 746 F.Supp.2d at 41 (“absent some context as to the . . . role and relationship

among the parties, the Court cannot say whether the communication was for legal advice, and in confidence and outside the presence of strangers”); *Merriweather v. United Parcel Service, Inc.*, 2018 WL 3572527, at *19 (W.D. Ky. July 25, 2018) (“Knowing the identity of each receiver of the document(s) is helpful in determining whether the documents are protected by privilege.”).

In particular, Fresenius’ failure to include information on the roles of individuals included on the privilege log who appear to be associated with third parties makes it impossible for the United States to assess whether the communication at issue was confidential. “Because attorney-client privilege applies only to confidential communications, it ‘will not shield from disclosure statements made by a client to his or her attorney in the presence of a third party.’” *United States v. Askins*, 2016 WL 4039204, at *5 (M.D. Tenn. July 28, 2016) (quoting *Reed v. Baxter*, 134 F.3d 351, 357 (6th Cir. 1998)). In a Florida district court decision, the court held an inadequate privilege log resulted in the waiver of the asserted privileges when the log “fail[ed] to identify the capacity of many recipients and [did] not provide sufficient information to assess the claim of privilege.” *Universal City Dev. Partners, Ltd. v. Ride & Show Eng’g, Inc.*, 230 F.R.D 688, 695-96 (M.D. Fla. 2005). With regard to an inadequate sample entry, the court explained that there was “no explanation of how . . . [an individual who was] apparently in-house counsel [to the defendant] could have an attorney-client relationship with an apparent third party.” *Id.*; see also *Firefighters’ Ret.*, 2018 WL 305604, at *7 (privilege log inadequate when “the inclusion of individuals who appear to be third parties makes the question of whether the communication was between client and counsel and whether the communication was intended to be confidential a closer call.”).

Similarly, the Third Privilege Log has multiple entries involving persons who are apparent third parties, without explaining how an attorney-client relationship exists. For example, entry FMCRx-MDTN-Priv3-00000222 is an email addressed to a person with the email address

“nconnell@amgen.com,” who is apparently associated with third party, Amgen. The email subject is: “scheduling call with Fresenius and Amgen legal teams,” and the privilege description states:

Email seeking legal advice and conveying request for legal advice regarding Fresenius and Amgen call regarding Next Generation contract.

McIntyre Decl., Ex. 20 at FMCRx-MDTN-Priv3-00000222. Without more information on the third party recipient of this communication, the United States cannot assess Fresenius’ privilege assertion about whether the communication was between client and counsel or was intended to be confidential. Therefore, the Third Privilege Log is deficient due to its failure to include information on the roles of third parties.

Fresenius’ refusal to provide information on non-legal persons also impedes the United States’ ability to assess whether internal distributions were sufficiently limited to maintain the confidentiality of the documents that Fresenius asserts are privileged. In the corporate setting, “the [attorney-client] privilege applies to communications by any corporate employee regardless of position” so long as “the communications concern matters within the scope of the employee’s corporate duties and the employee is aware that the information is being furnished to enable the attorney to provide legal advice.” *In re Perrigo*, 128 F.3d 430, 437 (6th Cir. 1997) (quotation omitted) (emphasis added); *see also Upjohn v. United States*, 449 U.S. 383, 394 (1981). Any party asserting privilege, however, must show “the communications contain confidential information and have been maintained in confidence,” or else the privilege will be waived. *Veiga*, 746 F. Supp. 2d at 34. In the corporate context, this means that distribution of documents should be limited to a “need to know” basis. *See FTC v. GlaxoSmithKline*, 294 F.3d 141, 148 (D.C. Cir. 2002); *see also Royal Surplus Lines Ins. v. Sofamor Danek Groups*, 190 F.R.D. 463, 476-77 (W.D. Tenn. 1999) (email messages with in-house counsel discoverable when there was “no indication . . . whether circulation of these e-mails was limited to those persons with a need to know”).

Without having basic information regarding recipients' roles and responsibilities, the United States cannot assess whether document distribution was limited to individuals with a need to know. *Cf. Reinhard v. Dep't of Homeland Sec.*, 2019 WL 3037827, at *15 (D.D.C. July 11, 2019) (description of individuals' "general role within the organization" permitted the court to "draw a reasonable inference that the non-attorney individuals fall within the realm of those protected by privilege," except with respect to one individual "whose position and role is not otherwise explained"). This analysis is particularly critical to assessing Fresenius' privilege claims given the "massive distribution of some documents," which raises questions about whether "confidentiality of whatever was revealed [was] actually maintained." *Motorola Solutions, Inc. v. Hytera Communications Corp.*, 2018 WL 1281393, at *1 (N.D. Ill. Jan. 10, 2018) (inadequate privilege log included communications distributed to, respectively, "over 200 recipients" and over "four dozen recipients"). The Third Privilege Log includes one document that was distributed to over a hundred recipients. *See McIntyre Decl.*, Ex. 20a at FMCRx-MDTN-Priv3-00003669. And roughly 23 percent of the email families on the Third Privilege Log were sent to a dozen or more recipients. *McIntyre Decl.*, ¶ 41. Therefore, the Third Privilege Log is deficient due to its failure to include information about the roles of non-legal employees within Fresenius.

B. The Third Privilege Log Does Not Include Sufficient Information regarding the Purpose and Subject Matter of Documents over which It Asserts Privilege

The Third Privilege Log is also deficient because the document descriptions are too vague to assess if the asserted privileges apply. A privilege log must explain the "purpose and subject matter" of the document. *Polylok*, 2017 WL 1102698, at *6. The log cannot merely recite the subject line of an email or the subject of a document. *See Ypsilanti Cmty. Utils. Auth. v. Meadowstvacco Air Sys. LLC*, 2009 WL 3614997, at *3-4 (E.D. Mich. Oct. 27, 2009). And a log must provide more than "empty recitations of the applicable legal standard devoid of factual

context.” *Veiga*, 746 F. Supp. 2d at 40 (privilege log entries were so “conclusory that [they] stymie[d] the Court’s ability to assess the basis for any claimed privilege”). Rather, log entries asserting the work product doctrine must identify the litigation the underlying document concerns. *See id.* (party asserting attorney work product “fail[ed] to carry his burden of demonstrating” the elements of work product applied because the privilege log did not “even attempt to identify which litigation or litigations the communications concern.”). Similarly, attorney-client privilege assertions must specify “the nature of the legal issue for which advice is sought.” *In re Search Warrant Executed at Law Offices of Stephen Garea*, 1999 WL 137499, at *1 (6th Cir. Mar. 5, 1999). The Third Privilege Log fails to include these required elements.

1. Fresenius’ assertions of work product are insufficient because the relevant entries do not attempt to establish the documents were prepared in anticipation of litigation

The Third Privilege Log is inadequate with respect to its assertions of attorney work product because the entries do not indicate the document was prepared or obtained in anticipation of litigation. “[A]n entry in a privilege log claiming protection under the work product doctrine requires a showing that the document was prepared or obtained because of the prospect of litigation.” *Osborn v. Griffin*, 2013 WL 5221663, at *2 (E.D. Ky. Sept. 17, 2013). Consequently, to adequately describe the subject and purpose of a document protected by the attorney work product doctrine, the privilege log should identify the litigation about which the communication concerns. *See Veiga*, 746 F. Supp. 2d at 40; *Nurse Notes, Inc. v. Allstate Ins. Co.*, 2011 WL 2173934, at *4 (E.D. Mich. June 2, 2011) (requiring revised privilege log with “more detailed descriptions as to which litigation it relates”).

The Third Privilege Log asserts the attorney work product doctrine applies to 161 documents, but these entries do not even attempt to reference a litigation. For example, Fresenius

asserts attorney work product over an email with the subject, “Re: Fw: OIG Alert on co-pay Card Programs.” The privilege description for this email states:

Email chain seeking and containing legal advice and containing legal advice [sic] and strategy of counsel regarding co-pay card programs; counsel includes Doug Kott, Domenic Gaeta, and Jeffrey Handwecker of Arnold Porter.

McIntyre Decl., Ex. 20a at FMCRx-MDTN-Priv3-00004306. This entry is clearly deficient with respect to the assertion of attorney work product, because it does not attempt to identify which litigation the email supposedly concerns.

Fresenius’ other 160 assertions of attorney work product are similarly deficient. While these entries include conclusory references such as “legal advice” or “strategy of counsel,” none of them indicate that the documents were prepared in anticipation of litigation. Indeed, none of them even reference the word “litigation,” a particular litigated matter, or disputes that faced potential litigation.⁷ Rather, the vast majority of these entries provide descriptions of subject matters that appear to relate to business operations, such as policies or forms, business agreements, audits, marketing brochures, or the patient financial assistance programs that are at issue in HHS-OIG’s investigation. *See generally id.*, ¶ 37 & Ex. 22 (Work Product Log) Therefore, the Third Privilege Log is deficient as to all assertions of work product, because the relevant entries do not identify any litigation the documents concern. *See id.*

⁷ Curiously, Fresenius failed to assert the attorney work product over emails for which the subject field explicitly referred to litigation or a specific litigated case. *See, e.g.*, McIntyre Decl., Ex. 20a at FMCRx-MDTN-Priv3-00001835 (email subject described as “Updated Q&A regarding Amgen/Hospira Litigation”); FMCRx-MDTN-Priv3-00001853 (email subject described as “MARCELLO S. LEE VS. DAVITA HEALTHCARE PARTNERS, INC; FRESENIUS USA MANUFACTURING, INC., ET AL,” and the privilege field described as “Email conveying request for legal advice regarding Lee v. Davita and Fresenius case.”).

2. The Third Privilege Log consistently fails to specify the nature of the legal issue in communications over which the attorney-client privilege is asserted

The Third Privilege Log is replete with assertions of attorney-client privilege that are entirely insufficient, because they do not specify the nature of the legal advice sought in the underlying documents. When asserting this privilege, a privilege log must specify “the nature of the legal issue for which advice is sought.” *Search Warrant*, 1999 WL 137499, at *1.

In *Firefighters’ Retirement System*, a court found privilege log entries were adequate when they specified the nature of the legal issue for which advice was sought, such as interpretations of specific provisions included in corporate or transaction documents, responses to inquiries from regulatory agencies related to a specific matter, or the legal implications of certain corporate actions. *See Firefighters’ Ret.*, 2018 WL 305604, at *6 (sufficient entries included descriptions such as: “email with counsel reflecting and requesting legal advice re: interpretation of Offering Memorandum concerning investment manager requirements related to NAV backlog;” “email to counsel requesting legal advice re: draft response letter to SEC information request of Fletcher funds;” “email from counsel reflecting and requesting legal advice re: analysis of [entity’s] ability to terminate ISDA agreement and implications of early termination of Global Hawk investment”).

In contrast, Fresenius’ Third Privilege Log is saturated with entries containing subject descriptions that are too vague to determine the nature of the legal issue for which legal advice was purportedly sought. The very first entry on the Third Privilege Log exemplifies the deficiencies that appear systemically throughout the log. This entry describes an email with the subject – “Agenda for today’s Bone Mineral Metabolism Initiative Weekly Status Call” – and includes the following privilege description:

Email providing information to counsel for the purpose of obtaining legal advice and conveying request for legal advice regarding bone mineral metabolism initiative.

See McIntyre Decl., Ex. 20a. The entry is deficient due to its total lack of information on the bone mineral metabolism initiative and requires speculation about what legal issues and what legal advice was supposedly sought. *Cf. Osborn*, 2013 WL 5221663, at *2-4 (privilege log subject description – “Notes re: Estate assets” – was inadequate because it “require[d] the court to speculate on the nature and subject of the documents,” including “as to what estate is referenced.”).

The insufficient detail regarding the subject is not cured by Fresenius’ conclusory statement that the email is for “legal advice.” *See id.* (description – “[l]egal analysis re: of [sic] JLG Estate assets” – was “too vague to inform the Court or the [party requesting the document] of the purpose of the document”). *Cf. also Search Warrant*, 1999 WL 137499, at *1 (upholding decision denying privileged status to document based on privilege log entry stating, “Third party document(s) transmitted by client to counsel for legal advice.”).

Moreover, nothing in the privilege log entry indicates the “bone mineral metabolism initiative” relates to a legal issue, rather than a business issue. The Sixth Circuit has held that “[i]t is, of course, well established that attorney-client communication related to areas other than legal counseling, such as business advice, are not privileged.” *Phipps v. Wal-Mart Stores, Inc.*, 2018 WL 1183746, at *3 (M.D. Tenn. Mar. 7, 2018) (quoting *Search Warrant*).

The first entry reflects the same deficient approach that Fresenius formulaically repeated thousands-upon-thousands of times throughout its Third Privilege Log. The entries specify a document type (such as an email or spreadsheet) then parrots empty recitations relevant to the legal standard, such as the document was for the purpose of “legal advice,” before concluding with a vague description of the subject matter of the document that does not specify the nature of legal issue. *See generally McIntyre Decl.*, Ex. 20a-d. As Fresenius well knows, trying to assess vague descriptions formulaically deployed across more than 12,000 privilege log entries is infeasible and

impracticable. The United States has identified representative examples of entries that appear to describe documents relating to the co-payment waiver, write-off, and refill issues under investigation, but that do not sufficient identify the nature of the legal issue. *See id.*, Ex. 23 (Sample Log). Despite the repetitive and rambling formula Fresenius reiterates across more than 12,000 privilege log entries, these entries fail to describe the subject and purpose of the documents with sufficient detail to specify the nature of the legal issue about which advice is sought.

C. Fresenius Has Not Provided Sufficient Information to Assess whether Numerous Documents over which It Has Asserted Attorney-Client Privilege Were Sent or Received by Professional Legal Advisors for Legal Advice

Fresenius' Third Privilege Log also includes many entries asserting attorney-client privilege, but those entries were not sent from or to a professional legal advisor. This is significant, because the attorney-client privilege applies only to communications with "a professional legal adviser in his capacity as such." *Phipps*, 2018 WL 1183746, at *2; *Ohio A. Philip Randolph Institute v. Smith*, 360 F. Supp. 3d 681, 691-92 (S.D. Ohio 2018) (party did not meet burden to establish attorney client privilege when "[s]ome of the documents do not even appear to be communications between clients and attorneys") (emphasis in original).

Fresenius withheld approximately 954 emails listed on the Third Privilege Log – equating to about 19 percent of all email families on the log – that were not sent from a legal professional and were not addressed to, or even copied to, a legal professional. *See McIntyre Decl.*, ¶ 39. To the extent that portions of prior communications in the email chain were privileged, Fresenius "should, at a bare minimum, be aware of [its] obligation to redact and produce non-privileged portions of responsive documents." *Veiga*, 746 F. Supp. 2d at 43-44 n.19. Therefore, the Third Privilege Log is deficient with respect to these entries, since it does not explain why documents

that were not sent or received by legal professionals are being withheld on the basis of attorney-client privilege.

In approximately 599 other instances – equating to about 12 percent of all email families on the log – Fresenius hinges its attorney-client privilege assertions solely on the fact that an attorney is *copied* on an email. But courts often require a higher level of detail in and scrutiny of attorney-client privilege assertions when a lawyer is only copied, because it is less clear that the communication was for the purpose of legal advice. *See, e.g., Firefighters’ Ret.*, 2018 WL 305604, at *7 (requiring *in camera* review of twenty-one documents in which counsel appeared in copy only despite “detailed” privilege log entries because “it is unclear whether these communications were actually confidential communications to a lawyer” for the purpose of legal, not business advice); *see also In re Avandia Mktg., Sales Practices & Prod. Liab.*, 2009 WL 4807253, at *6 (E.D. Pa. Oct. 2, 2009) (email that “arguably contained a request for legal advice” was not privileged because the email only copied an attorney); *Affordable Bio Feedstock, Inc. v. Darling Int’l Inc.*, 2012 WL 5845007, at *3, 5 (M.D. Fla. Nov. 19, 2012) (email copying attorney was not privileged because the party asserting privilege “could not prove that the primary purpose of the communication was for “legal advice or assistance”); *Zelaya v. UNICCO Serv. Co.*, 682 F. Supp. 2d 28, 39 (D.D.C. 2010) (“carbon copying some emails to in-house counsel will not provide the basis for attaching the attorney-client privilege”). For these roughly 599 entries, Fresenius’ conclusory recitations of the legal standard – without more detail to show that the predominant purpose of the document was seeking legal, rather than business, advice – are inadequate.⁸

⁸ Similarly, Fresenius attempts to assert attorney client privilege over communications based on the participation of an individual who does not appear to serve primarily as a legal advisor to Fresenius. The attorney-client privilege applies only to communications with “a professional legal adviser *in his capacity as such*.” *Phipps v. Wal-Mart Stores, Inc.*, 2018 WL 1183746, at *2 (emphasis added). The Second Index of Legal Persons identifies Ron Kuerbitz only as “Executive Officer for FMCNA.” While some descriptions in the Third Privilege Log refer to Kuerbitz as “counsel,” Fresenius may not assert privilege

III. WAIVER OF PRIVILEGE IS AN APPROPRIATE REMEDY HERE

Fresenius' repeated production of massive privilege logs with egregious deficiencies is an inappropriate and prejudicial delay tactic. The persistent deficiencies that remain in Fresenius' Third Privilege Log – even after two opportunities for revisions – call for a waiver of the privileges asserted. “When a party supplies an inadequate privilege log, there are four possible remedies. The court can (1) provide the party another chance to submit a more detailed log; (2) deem the inadequate log a waiver of the privilege; (3) conduct an *in camera* inspection of the withheld documents; or (4) conduct an *in camera* inspection of a subset of the withheld documents.” *NLRB v. NPC Int’l, Inc.*, 2017 WL 634713, at *9 (W.D. Tenn. Feb. 16, 2017). Waiver is an appropriate sanction for a party’s failure to produce an adequate privilege log when “a court finds that the failure results from unjustified delay, inexcusable conduct, or bad faith.” *Fresenius Medical Care Holdings, Inc. v. Hood*, 269 So. 3d 36, 56 (Miss. 2018).

Waiver is the appropriate here for two reasons. First, it would be nonsensical and futile to give Fresenius a fourth chance to revise its privilege log with no negative repercussions. This would incentivize parties like Fresenius to continue to submit deficient logs and still get another chance to revise them without penalty. Second, Fresenius' repeated failures to produce an adequate privilege log have unjustifiably delayed HHS-OIG's investigation, making waiver the best option here. Courts have held privilege waived when a party failed to produce an adequate privilege log within several months of the response deadline. *See Nationwide Mut. Fire Ins. Co. v. Kelt, Inc.*, 2015 WL 1470971, at *9 (M.D. Fla. Mar. 31, 2015) (privilege waived for certain documents when the party “took over a month after its initial responses to . . . serve its inadequate

over “non-legal communications where the attorney acts as a business or economic advisor.” *Edwards v. Whitaker*, 868 F. Supp. 226, 228 (M.D. Tenn. 1994).

privilege log”); *Universal City*, 230 F.R.D. at 695-96 (inadequate log waived privilege when produced eight months after responses were due). By thrice producing inadequate privilege logs, Fresenius has delayed HHS-OIG’s investigation more than fifteen months after Fresenius supposedly completed its email production on October 22, 2018, when Fresenius produced its First Privilege Log. *See* McIntyre Decl., Ex. 7. After the United States noted deficiencies with that log, Fresenius took nearly three months to provide the Second Privilege Log. After the United States identified deficiencies in that log too, Fresenius took another two months to produce its Third Privilege Log. *See id.*, Ex. 19.

Deficiencies in the Third Privilege Log continue to delay HHS-OIG’s investigation by requiring the United States to seek the present enforcement petition. The United States has expended considerable resources attempting to review Fresenius three deficient privilege logs. *See id.*, Ex. 18, 23, 35 & 40-42. And now, the United States and this Court will be required to spend substantial additional resources if required to attempt to analyze and determine Fresenius’ privilege claims based on its summary descriptions. *Cf. Baxter Travenol Labs., Inc. v. Abbott Labs.*, 1987 WL 12919, at *1 n.1 (N.D. Ill. June 18, 1987) (privilege log listed documents in “such a summary fashion that hundreds of hours have been required to evaluate” its privilege claims). Fresenius’ stonewalling tactics have already significantly prejudiced the United States. The long delay here is stymying HHS-OIG’s investigation. Therefore, waiver is an appropriate remedy.

Fresenius’ persistent failures to produce an adequate privilege also reflect a lack of good faith that supports waiver. Fresenius blatantly disregarded privilege log requirements just weeks after it was sanctioned for similar privilege log deficiencies in Mississippi. Courts have imposed waivers for inadequate privileges logs when the party asserting privilege has repeatedly disregarded discovery rules or judicially developed guidance on privilege log requirements. *See*

In re Haynes, 577 B.R. 711, 736 & 740 (E.D. Tenn. 2017) (holding party’s continued failure to produce a privilege log that complied with Federal Rule of Civil Procedure 26 and with court orders after initial 115 day delay and “multiple chances to do so constitutes a waiver of the objection to the production of documents”); *see also Mafcote*, 2010 WL 1929900, at *5-7 (privilege waived if logs not made complete within 21 days and attorney’s fees awarded when counsel did not research case law providing guidance on privilege log requirements, but rather “preferr[ed] to wait for [the] court to opine before providing details”). Now on its third privilege log, Fresenius appears to prefer to wait for the United States to identify deficiencies rather than independently complying with clear privilege log rules. While Fresenius has complained about the burden of revising its privilege logs,⁹ these efforts could have been avoided if Fresenius had researched and followed guidance on the standards applicable to privilege logs on its first effort.

The shortcomings in Fresenius’ privilege logs are particularly egregious given that Fresenius produced the First Privilege Log just eighteen days after a waiver sanction was upheld against Fresenius for failing to provide an adequate privilege log. On October 4, 2018, the Supreme Court of Mississippi upheld a decision imposing a sanction of privilege waiver against Fresenius for failing to produce an adequate privilege log covering over 3000 withheld entries to the State of Mississippi in connection with litigation under the Mississippi Consumer Protection Act. *See generally Hood*, 269 So. 3d 36. Since February 2016, Fresenius had defended against a series of motions to compel that were brought based on various issues and deficiencies in its privilege logs. *Id.* Some of the disputed issues were: Fresenius’ inclusion of non-responsive

⁹ The volume of documents Fresenius needs to review for privilege is substantial due to the e-discovery methodology Fresenius itself developed and proposed. *See supra* at 4-5. It cannot now escape its obligations to produce an adequate privilege log by claiming that the volume associated with the privilege review resulting from a methodology it designed is too burdensome.

documents in the privilege log; its “family logging” method that failed to log email attachments and unique emails within in a chain separately; its failure to include authors and recipients on hundreds of documents; its inclusion of entries without any counsel; and its failure to include descriptive information for various attachments. *Id.* at 52-57.

Despite this 2.5 year battle, less than three weeks after the decision from the Supreme Court of Mississippi, Fresenius produced the First Privilege Log in response to HHS-OIG’s Subpoenas that included many of the same deficiencies that had been addressed in the *Hood* matter. Now it has produced two more versions of logs that retain many of these deficiencies. Like the logs at issue in *Hood*, Fresenius’ privilege logs have failed to include information on the roles of authors and recipients; failed to log emails and attachments separately; failed to provide various factual information regarding attachments; and included numerous entries without counsel. *See McIntyre Decl.*, Ex. 8 & 11. Fresenius’ disregard for clear privilege log requirements demands, at a minimum, a waiver of the asserted privilege. *See Mafcote*, 2010 WL 1929900, at *5-7 (inadequate privilege log could result in sanction of waiver and attorney’s fees when counsel “[did] not appear to have attempted to locate [privilege log] guidance”).

Moreover, courts typically do not conduct an *in camera* review when the party asserting privilege has not yet “provided sufficient factual information to justify the privilege/protection claimed for each document.” *See Haynes*, 577 B.R. at 738-41 (collecting cases noting the enormous burden on a court from an *in camera* review); *AVX Corp. v. Horry Land Co.*, 2010 WL 4884903, at *4 (D.S.C. Nov. 24, 2010) (noting that “[i]t is not the duty of the court to sift through the numerous documents presented and attempt to discern which privileges or protections may apply to any given document or portion of a document” and ordering production of withheld records). Further, conducting an *in camera* review of the 12,542 documents listed on the Third

Privilege Log is not an appropriate use of judicial resources. *Lurensky v. Wellingshoff*, 2010 WL 11586783, at *10 (D.D.C. 2010) (“[I]n camera review, because of the burden it places on the Court, should be the exception, and not the norm.”). Thus, Fresenius’ unjustified delay and bad faith demands a remedy of waiver.

Alternatively, the United States respectfully asks the Court to first, conduct an *in camera* review of the fifty emails identified on the Sample Log included at McIntyre Decl., Ex. 23 and the corresponding attachments and then, enter an order as to those Sample entries. Assuming that the Court’s order finds at least some of these documents are not privileged or should be redacted, the United States requests that the Court order Fresenius to produce all non-privileged documents consistent with this Court’s findings on the Sample Log. In addition, the United States requests that the Court’s order address the widespread deficiencies remaining in Fresenius’ Third Privilege Log, including Fresenius’: (1) failure to identify authors and recipients included on the privilege log; (2) failure to identify any potential litigation at issue in documents over which it asserts attorney work product; (3) failure to provide specify the nature of the legal issue addressed in documents over which it asserts attorney-client privilege; (4) failure to provide sufficient information to assess why more than one thousand documents that were not sent to or from a legal advisor are withheld on the basis of attorney-client privilege; and (5) failure to provide log explaining its basis for withholding the GDPR Documents. Finally, the United States requests that the Court’s order require Fresenious to produce a fully compliant privilege log within 21 days with the condition that “[a]nything less than full compliance by [Fresenius] will result in waiver of any privilege.” See *Polylok*, 2017 WL 1102698, at *6; *McGee*, 2017 WL 1232616, at *3-4 (party that produced an inadequate privilege log of thousands of entries was ordered to provide “fully compliant” privilege log within ten days or else face potential waiver.).

CONCLUSION

The Subpoenas should be summarily enforced. They satisfy the terms of the Inspector General Act because they were issued by HHS-OIG to carry out its responsibility to prevent and detect fraud and abuse. They seek documents relevant to HHS-OIG's inquiry, and they are not unreasonable or burdensome. Enforcing them would not abuse the court's process, because they were issued in the good faith pursuit of HHS-OIG's investigation. The United States respectfully requests that the Court find Fresenius' Third Privilege Log is inadequate, because it does not provide sufficient information to determine whether the documents are covered by the attorney-client privilege or the attorney work product doctrine. Furthermore, because Fresenius' failure to provide an adequate privilege log after three attempts has resulted in unjustified delay and it has exhibited bad faith by disregarding requirements for privilege logs, the United States requests that the Court hold Fresenius has waived the privileges asserted in the Third Privilege Log. Alternatively, the United States requests that the Court order Fresenius to provide documents identified in the Sample Log, Exhibit 23, for an *in camera* review, and produce any non-privileged documents and a fully compliant privilege log within 21 days of the Court's order on the Sample Log entries. A proposed order is attached.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Memorandum was served via First Class U.S. Mail, postage prepaid, and/or via email on February 24, 2020.

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